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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,054

03/22/2006

Anthony Robert Milnes Coates

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

SWARTZ, RODNEY P

ART UNIT

PAPER NUMBER

1645

MAIL DATE

DELIVERY MODE

08/11/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/534,054	Applicant(s) COATES, ANTHONY ROBERT MILNES	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-35 and 37-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-35 and 37-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12 June 2009 has been entered.

Claims 31, 34, 35 and 37 have been amended.

2. Claims 31-35 and 37-53 are pending and under consideration.

Rejections Withdrawn

3. The rejection of claims 31-34 and 38 under 35 U.S.C. 112, second paragraph, as being indefinite for "derived", is withdrawn in light of the claim amendments.

4. The rejection of claims 34, 35, 37, and 38 under 35 U.S.C. 112, second paragraph, as being indefinite for sequences, is withdrawn in light of the claim amendments.

Rejections Maintained

5. The rejection of claims 34, 35, 37, and 38 under 35 U.S.C. 112, first paragraph, scope of enablement for any/all fragments of said heat shock proteins providing pain relief, is maintained for reasons of record.

Applicant argues that: 1) the structural characteristic of the chaperonins 60 and 10 are well-established in the art, 2) *M. tuberculosis* is known to produce chaperonin 60.1, 60.2 and 10, and 3) chaperonin 60.2 exhibits 59.6% identity to cpn 60.1 protein.

Using Tormay et al (*J. biolog. Chem.*, 280(14):14272-14277) as a reference, applicant argues that it would be a matter of routine experimentation to test the claimed nucleotides and claimed polypeptides for their pain relief characteristics.

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The examiner has considered applicant's arguments, but does not find them persuasive. As put forth in the original rejection explanation, the specification utilizes only whole cpn 60.1, cpn 60.2 or cpn 10 and does not direct a person of skill in the art to any particular part (subsequence) which is the critical component to be retained in order to achieve the claimed results.

The cited reference, i.e., Tormay et al, is not directed to determining pain relief, but domains involved in intercellular signaling and activating.

Thus, the rejection is maintained because there is no direction or evidence that any subsequence of the whole proteins can be utilized and retain all of the claimed activity.

6. The rejection of claims 31-35 and 37-53 under 35 U.S.C. 112, first paragraph, scope of enablement for relieving pain by administration of polynucleotides encoding a heat shock polypeptide, is maintained for reasons of record.

Applicant argues that: 1) the structural characteristic of the chaperonins 60 and 10 are well-established in the art, 2) *M. tuberculosis* is known to produce chaperonin 60.1, 60.2 and 10, and 3) chaperonin 60.2 exhibits 59.6% identity to cpn 60.1 protein.

Using Tormay et al (*J. biolog. Chem.*, 280(14):14272-14277) as a reference, applicant argues that it would be a matter of routine experimentation to test the claimed nucleotides and claimed polypeptides for their pain relief characteristics.

The examiner has considered applicant's arguments, but does not find them persuasive. As put forth in the original rejection explanation, the specification utilizes only whole cpn 60.1, cpn 60.2 or cpn 10 and does not direct a person of skill in the art to any particular part (subsequence) which is the critical component to be retained in order to achieve the claimed results.

Art Unit: 1645

The cited reference, i.e., Tormay et al, is not directed to determining pain relief, but domains involved in intercellular signaling and activating. In addition, Tormay et al is drawn to protein, not nucleic acid sequences.

Thus, the rejection is maintained because there is no direction or evidence that any subsequence of the whole nucleotides can be utilized and retain all of the claimed activity.

Conclusion

7. No claims are allowed.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

August 11, 2009